II. REMARKS

The Examiner acknowledges proof of co-pendency to parent application and as such, has withdrawn the objection to priority.

Claims 1-4 stand rejected under 35 U.S.C. 112, first paragraph. The examiner states that the specification, while being enabling for the specific pharmaceutically acceptable excipients disclosed, does not reasonably provide enablement for pharmaceutically acceptable excipients in general and the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants respectfully disagree.

The examiner states that the prior art of record appears to use similar excipients but according the specification does not result in tablets having the same properties as the present invention. The examiner concludes that predictability in the art appears to be low.

But the similarity or not of excipients with those of the prior art is not the crux of applicants invention. As stated succinctly in the first paragraph of the Summary,

> Accordingly, it is an object of the present invention to provide an improved rapidly disintegrable tablet for oral administration comprising a pharmacologically active ingredient, spray-dried mannitol and crospovidone.

Thus, applicants' invention is limited to tablets which contain a pharmacologically active ingredient, spray-dried mannitol and crospovidone. The spray-dried mannitol and crospovidone are identified as disintegrants in part (ii) and (iii) of claim 1, as distinguished from excipients identified in part (iv) of the claims. Thus, as is recognized in the specification and by those skilled in the art, there are numerous possible pharmaceutically acceptable excipients that are typically used in the tabletting art and the presence or absence of those excipients is not a part of this invention provided spray-dried mannitol and crospovidone are present.

The examiner states that the claims are broad to the extent that there is no indication as to the scope of pharmaceutically acceptable excipients. The examiner states that it appears that one of ordinary skill in the art would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims, i.e. determine what other pharmaceutically acceptable excipients will result in a tablet which disintegrates within 60 seconds.

Applicants respectfully disagree.

It is not a question of what other pharmaceutically acceptable excipients will result in a tablet which disintegrates within 60 seconds – applicant has specifically described what components of the tablet are responsible for providing a tablet which disintegrates within 60 seconds [spray-dried mannitol and crospovidone] – the excipients play no role in providing the 60 second disintegration time and merely act as sweeteners, lubricants, etc.

Applicants request reconsideration.

Claims 1-4 stand rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements as set forth in MPEP § 2172.01. The examiner states that the omitted elements are: (1) spray dried-mannitol and crospovidone need to be present in amounts sufficient to cause disintegration of the tablet within 60 seconds (Pg. 3, lines 23,24, Pg. 5, lines 24,25, Pg. 6, Pg. 7, lines 1-4); (2) does not leave significant amounts of water-insoluble matter and is having a hardness such that it is not friable during handling or shipment (Pg. 3, lines 10-16, Pg. 7, lines 24,25, Pg. 8, lines 1).

With regard to element (1), Applicants have amended claim 1 to identify the spray dried-mannitol and crospovidone as disintegrants and to require the presence of an effective amount of each.

With regard to element (2), the claims define a composition of matter having 4 components. The claim also indicates the intended use of the composition – as a tablet for oral administration that dissolves in 60 seconds. It is true that other benefits accrue with the use of the inventive composition; there is no residue of insolubles, the tablets are not friable, the active ingredient can be administered to patients who must restrict their intake of water, the active ingredient can be

administered to patients who have deglutition difficulties, etc . Inherent features of the composition such as the recited characteristics or its weight or color are not required to be set forth in a claim when they are not stated as being essential in the specification, nor are the intended uses required in a composition claim.

As stated in the first paragraph of the summary, set out above, it is the rapid disintegration that is the crux of the invention – the lack of water insoluble matter and lack of friability are not mentioned. Thus, these are not essential elements as required by 35 USC 112 2nd paragraph and do not need to be specified in the claim.

Reconsideration of this ground of rejection is requested.

Any fee due with this paper, not fully covered by an enclosed check, may be charged on Deposit Account 50-1290.

Respectfully submitted,

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